DEPARTMENT OF HEALTH & HUMAN SERVICES

95084d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 1000100733

November 19, 2004

Michael J. Weinberg-Lynn, President
Osprey Seafood of California Inc.
Pier 33
San Francisco, California 94111

WARNING LETTER

Dear Mr. Weinberg-Lynn:

On August 24 and 25, 2004, we inspected your seafood processing facility, located at Pier 33, San Francisco, California. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly the following products are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health:

- Fresh tuna (Yellow fin, Big Eye, Blue fin, and Albacore)
- Mahi-Mahi

You may find the Act and the Seafood HACCP Regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for Scombrotoxin Fish Species lists a monitoring procedure at the storage critical control point that is not adequate to control histamine formation. FDA recommends continuous temperature monitoring of refrigerated storage by means of recorder thermometers, time/temperature integrators, high temperature alarms, maximum indicating thermometers, or digital data loggers,

with a visual check at least once per day. If you are using ice or cooling media to completely surround product, this is considered a continuous application of cooling, and you should check the adequacy of ice or cooling media at least twice per day.

2. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for Scombrotoxin Fish Species at the storage critical control point to control histamine formation is not adequate because it does not also include evaluation of the product(s) for histamine formation.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP Regulations, and the Current Good Manufacturing Practice Regulations (21 CFR 110).

During the inspection, FDA collected FDA Sample No. 220186, H&G Mahi-Mahi. FDA organoleptic analysis found 17 of the 18 subs decomposed. The product was adulterated within the meaning of Section 402(a)(3) of the Act. We acknowledge that you voluntarily destroyed the remaining lot of product. We recommend that you follow up on this issue with your supplier, [redacted]

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Please send your reply to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Barbara J. Cassens
District Director
San Francisco District

Enclosure: Form FDA 483